THE SCIENCE BEHIND THE T-SPOT®.*TB* TEST

Accurate across patient populations

- Effective in challenging patient populations[1]
  - Immunocompromised
  - BCG-vaccinated
- Only TB test with sensitivity and specificity > 95%[1]
  - Sensitivity: 95.6%
  - Specificity: 97.1%
- FDA-approved borderline zone provides test resolution for results around the cut-off point[2, 3]

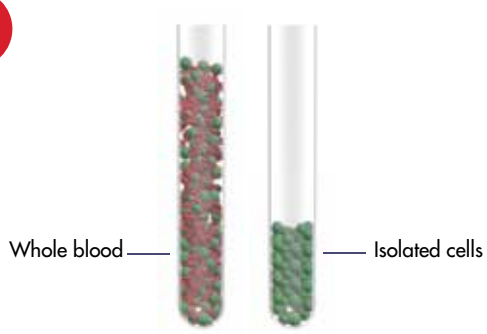
Consistent results

- Invalid rate of 0.6% in a study of > 645,000 tests[2]
- 98.9% concordance and 0.8% mean conversion rate in a study of > 42,000 healthcare worker serial tests[4]

One tube with no refrigeration[1]

- Standard phlebotomy
- One visit
- No on-site pre-analytical steps
- No on-site incubation or refrigeration

1

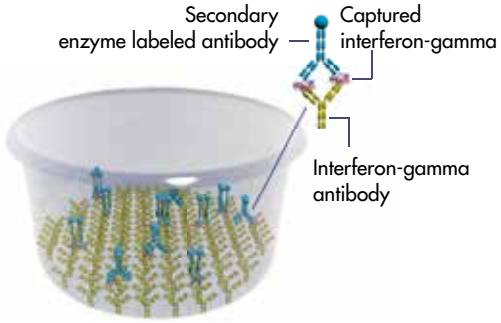


A blood specimen is collected using routine phlebotomy and a standard blood collection tube from which a subset of white blood cells, known as peripheral blood mononuclear cells, are isolated. The cells are washed, counted and normalized to create a standard cell suspension.

2

A standard number of cells are added into specially designed plates and stimulated with TB-specific antigens, ESAT-6 and CFP10. Cells responding to these antigens release interferon-gamma.

3



Interferon-gamma antibodies are used to directly capture interferon-gamma as it is released by the cells. A secondary enzyme labeled antibody is added and binds to the captured interferon-gamma.

4

A detection reagent is added and reacts with the enzyme labeled antibody. This reaction produces spots, which are a footprint of where the interferon-gamma was released. Spots are then enumerated.

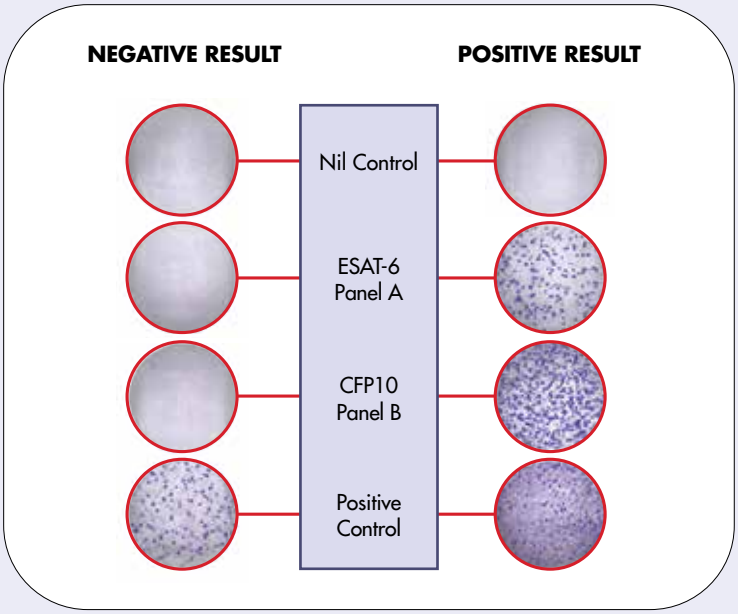
T-SPOT®.*TB*

A MOMENT OF TRUTH

Interpretation of results

- Interferon-gamma is captured and presented as spots from T cells sensitized to TB infection
- Results are interpreted by subtracting the spot count in the negative (NIL) control from the spot count in Panels A and B
  - Positive ≥ 8 spots
  - Negative ≤ 4 spots
  - Borderline 5, 6 or 7 spots
  - Invalid
- The inclusion of a borderline category is intended to reduce the likelihood of false-positive or false-negative results around the test cut-off

Note: It is recommended that borderline and invalid results be retested with a new specimen



Unique CPT® code[5]

The T-SPOT.*TB* test is the only commercially available TB blood test appropriate to be submitted under CPT code 86481.[1,6,7] The T-SPOT.*TB* test is a standardized test that requires cell enumeration.[1]

CPT code	86481*	86480*	86480*
Applicable test	The T-SPOT.*TB* test	QuantiFERON®-TB Gold Plus (QFT®-Plus)	LIAISON® QFT-Plus
Description	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension	Tuberculosis test, cell mediated immunity measurement of gamma interferon producing antigen response	Tuberculosis test, cell mediated immunity measurement of gamma interferon producing antigen response

* The listed CPT codes reflect Oxford Immunotec's general interpretation of CPT coding requirements and are provided for informational purposes only. OXFORD IMMUNOTEC DOES NOT PROVIDE CODING ADVICE AND ASSUMES NO RESPONSIBILITY FOR BILLING ERRORS DUE TO RELIANCE ON CPT CODES LISTED IN MATERIALS PROVIDED BY OXFORD IMMUNOTEC. It is the responsibility of the billing laboratory to determine the correct CPT code to use in light of the particular circumstances.

Visit **TSPOT.COM** for more information

REFERENCES:

1. Oxford Immunotec. T-SPOT.*TB* Package Insert PI-TB-US-0001 V7. Abingdon, UK. February 2019.
2. Rego K, Pereira K, MacDougall J, Cruikshank W. Utility of the T-SPOT®.*TB* test's borderline category to increase test resolution for results around the cut-off point. *Tuberculosis*. 2018;108:178-185. doi:10.1016/j.tube.2017.12.005.
3. Mazurek GH, Jereb J, Vernon A, LoBue P, Goldberg S, Castro K, IGRA Expert Committee, Centers for Disease Control and Prevention (CDC). Updated guidelines for using Interferon Gamma Release Assays to detect Mycobacterium tuberculosis infection - United States, 2010. *MMWR Recomm Rep*. 2010;59(RR-5):1-25.
4. King TC, Upfal M, Gottlieb A, Adamo P, Bernacki E, Kadlecek CP, Jones JG, Humphrey-Carothers F, Rielly AF, Drewry P, Murray K, DeWitt M, Matsubara J, O'Dea L, Balser J, Wrighton-Smith P. T-SPOT.*TB* Interferon-γ Release Assay Performance in Healthcare Worker Screening at Nineteen U.S. Hospitals. *Am J Respir Crit Care Med*. 2015;192(3):367-373. doi:10.1164/rccm.201501-0199OC.
5. American Medical Association. CPT 2016 Professional Edition. [Chicago, Ill.]: American Medical Association; 2015
6. Qiagen. QuantiFERON-TB Gold Plus (QFT-Plus) ELISA Package Insert. 1095849 Rev. 06. November 2019.
7. American Medical Association (2019). Knowledge Base. #7072.

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